

URINARY CATHETERIZATION KIT**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] N/A

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] N/A

BACKGROUND OF THE INVENTION

[0003] 1. Technical Field of the Invention

[0004] The present invention relates to devices and methods for catheterization of the urinary bladder.

[0005] 2. Description of Related Art

[0006] In hospital settings today, it is commonplace for nurses to perform catheterization procedures using convenience packs, or pre-assembled kits, which typically contain a vinyl or red latex rubber catheter, waterproof absorbent underpad, fenestrated drape, disposable gloves, a sealed packet containing about 22.5 mL of Povidone-Iodine solution, five prepping cotton balls in a disposable tray compartment, a sealed packet containing sterile lubricating jelly, a plastic forceps, a sterile specimen bottle, and a 1000 mL graduated basin. All of these items are packaged together and sterilized. In practice, a nurse opens the tray, dons sterile gloves and places the drape around the patient's genitalia. The Povidone-Iodine packet is opened and poured over the five cotton balls. The packet of lubricating jelly is opened and squeezed onto a sterile field. The patient's urethral opening is cleansed with the five saturated cotton balls, holding each with the forceps. The nurse then runs the tip end of the catheter, comprising the first inch or two (about 2.5 cm to about 5 cm) of the insertable portion, through the lubricating jelly. The catheter is then inserted into the urethra and advanced until urine begins to flow. The urine is drained into the receptacle. A urine specimen is caught in the collection container, if needed. The catheter is then removed and all items of equipment are discarded. Care must be taken to maintain sterile procedure, to reduce the risk of urinary tract infection. Because multiple steps are involved in the procedure, a nurse typically spends a significant amount of time (e.g., 10-15 minutes) carrying out each catheterization. This basic procedure is used in virtually every inpatient hospital around the world, and has remained essentially the same for 50 years.

[0007] The healthcare industry would welcome a way to simplify and streamline inpatient catheterization procedures and eliminate steps that may compromise sterile technique.

SUMMARY OF THE PREFERRED EMBODIMENTS

[0008] The representative embodiments disclosed herein seek to overcome some of the drawbacks inherent in the prior art by providing devices, kits and methods for simplifying and improving inpatient catheterization equipment and procedures. Accordingly, in certain embodiments, a urinary catheter assembly is provided which comprises a catheter having a urethra-insertable portion and a non-insertable portion. The insertable portion comprises a first end and an insertion stop location adjacent to the non-insertable portion,

wherein the non-insertable portion comprises a second end having a urine outlet. The assembly also includes a pliable sheath, or thin plastic bag, comprising a lumen, and enclosing all or part of the insertable portion of the catheter, and has a terminus that is attached to the catheter at an attachment point disposed between the insertion stop location and the outlet end of the catheter, to form a water-tight seal. In some embodiments the attachment point coincides with the outlet end of the catheter. The sheath lumen and the urine outlet of the catheter are prevented from mutual fluid communication, so as to prevent urine from entering the sheath interior or lumen, and to prevent urine from contacting the insertable portion of the catheter.

[0009] In certain embodiments, the catheter assembly further comprises a catheter tip guard or introducer that is attached to the opposite end of the sheath. Together the sheath and catheter tip guard, or the like, in cooperation, completely enclose the urethra-insertable portion of the catheter. In certain embodiments, at least part of the non-insertable portion of the catheter comprises an uncovered region of the catheter, which extends outside of the sheath. Thus leaving a exposed portion or "free end" of the catheter, including the urine outlet. The free end facilitates collection of urine specimens and facilitates drainage of urine into a urine receptacle. In some embodiments, the catheter assembly comprises a urine receptacle attached to the non-insertable portion of the catheter. In certain embodiments, the urine receptacle includes a urine drainage tube for conveniently obtaining a sterile urine specimen.

[0010] In some embodiments, the free end comprises substantially all of the non-insertable portion of the catheter. In certain embodiments, the sheath attachment point is spaced apart from the outlet end of the catheter a distance of no more than about $\frac{1}{3}$ of the total length of the catheter, wherein the $\frac{1}{3}$ distance comprises the free end or uncovered region of the catheter.

[0011] In some embodiments, the attachment point coincides with the outlet end of the catheter, or is spaced apart from the outlet end a distance (d) of no more than about 2 mm. Even a short length of exposed catheter outside of the sheath can serve as a useful lip for resting on the opening of a small container, to facilitate collection of a urine specimen.

[0012] In certain embodiments, the attachment point is spaced apart from the catheter outlet end a distance (d) in the range of about 2 mm to about 50 mm, preferably in the range of about 10 mm to about 30 mm.

[0013] In certain embodiments, the sheath terminus is sealingly attached to the attachment point on the catheter.

[0014] In certain embodiments, a catheter assembly is provided in which the sheath terminus is slidingly attached to the attachment point on the catheter.

[0015] In certain embodiments, a catheter assembly is provided in which an extension is attached to the sheath terminus, wherein the extension comprises a urine spout, to facilitate urine collection. In certain embodiments, the extension comprises a band attached to the sheath terminus at the attachment point.

[0016] In accordance with certain embodiments of the present invention, a catheterization kit is provided which comprises an above-described urinary catheter assembly in